

REMARKS

This submission is in response to the Official Action dated February 27, 2006. Claims 58, 60, 62-71, 89, 91-94, and 96 -124 are currently pending. Claims 58, 64, 89, 91- 93, 96, and 98 are amended herewith. Claims 103-124 are added. Claims 90 and 95 are canceled. Support for the amendment in claims 58, 89, 92- 93, 96, and 98 can be found in the specification, page 17, lines 28-29 and on page 18 lines 8 - 11. Support for the amendments to claims 89 and 92 can be found in the specification and in claims 90 and 95 as previously submitted. Claims 64 and 91 are amended to correct the dependency. Support for new claims 103 and 105 can be found in claim 58, 89 and 95 as previously submitted and in the specification at page 18, lines 3 - 5. Support for new claims 104 and 106 – 124 can be found in claims 89- 98 and in claims 60, 62-71, and 99-102. Reconsideration of the above-identified application, in view of the following remarks, is respectfully requested. Each of the Examiner's rejections is discussed below.

Rejections under 35 U.S.C. §102(e)

Claims 89, 92, 95, and 98 remain rejected as anticipated by U.S. Patent No. 5,681,802 to Fujiwara. The Examiner contends that the liquid skin cleanser of Fujiwara includes a cationic polymer and/or cationic surfactant, a metallic material as a preservative, and, inherently, a moisture-resistant film. The Examiner further states that there is no evidence that the prior art compounds cannot be rendered substantially water insoluble and that the art is replete with water insoluble metallic material that contain an alkali earth salt.

Applicants respectfully traverse this rejection. The claims as presently amended recite compositions containing antimicrobial metallic materials which are substantially water insoluble or can be rendered substantially water-insoluble by chemical reaction with an alkali halide. The claims do not encompass compounds that are not water insoluble and cannot be rendered such by a reaction with an alkali halide. The alkali or alkaline earth metal salts of surfactants and preservatives, i.e., the metallic materials described by Fujiwara are soluble in water. In particular, the salts NaCl, Na sulfonate, and potassium sorbate are each soluble in water. Fujiwara does not disclose the use of

any water insoluble metallic materials that contain an alkali earth salt (i.e., a material stated to be replete in the art by the Examiner), any other water insoluble metallic material, or their use in an anti-microbial composition. Further, any reaction between the alkali or alkaline earth metal salts of surfactants as described by Fujiwara with an alkali halide will not make the salt insoluble. In most cases, the two compounds will either not react or simply exchange the alkali ion with the alkali or alkaline earth ion (assuming the alkali ions are different).

Additionally, new claims 103 – 109 and 111 - 124 encompass compounds comprising a metal selected from the group consisting of silver, zinc, cadmium, lead, mercury, antimony, gold, aluminum, copper, platinum, and palladium. Fujiwara does not teach or suggest compositions containing antimicrobial metallic materials having any of these metals; the teachings of Fujiwara are limited to alkali or alkaline earth metals (see col. 4 line 67 – col. 5 line 2 and col. 5: 27 – 29).

Applicants respectfully submit that Fujiwara does not satisfy the requirements for anticipation. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegal Bros. v. Union Oil*, 814 F.2d 628 (Fed. Cir. 1987). Since Fujiwara does not teach compositions comprising an antimicrobial metallic material which is substantially water-insoluble, can be rendered substantially water-insoluble by chemical reaction with an alkali halide, or, alternatively, an antimicrobial material containing the claimed transition metals, Fujiwara cannot anticipate claims 89, 92, 95, or 98. Therefore, applicants respectfully request that the rejection under 35 U.S.C. §102(e) for claims 89, 92, 95, and 98 be withdrawn.

Rejections under 35 U.S.C. §103(a)

Claims 58, 60, 62-71, and 89-102 remain rejected as obvious over WO 95/17152 to Sawan in view of Fujiwara '802 and U.S. Patent No. 5,576,006 to Smith. The Examiner contends that the antimicrobial compound disclosed by Fujiwara, which may include a polymer and a metallic material, would be obvious to combine with the WO '152 patent, which teaches cross-

linking of PHMB with an organic compound to enhance the final activity, the use of silver salts, and topical use. The Examiner also argues that U.S. 5,576,006 to Smith is “complementary” to Fujiwara and WO ‘152 and provides the state of art for preparing topical PHMB-containing lotions. The Examiner argues that it would have been obvious to combine two compositions taught as useful for the same purpose and therefore combining the Fujiwara and the WO ‘152 compositions would have been obvious.

Applicants respectfully traverse this rejection. WO ‘152 provides liquid dispensers that prevent microbial contamination and teaches that this is accomplished using an integral, non-leaching antimicrobial element such as a filter in the liquid dispenser (see pg 3 lines 4 – 7). A topical agent can be administered using this dispenser. WO ‘152 teaches away from the method of the currently pending claims in two ways:

First, WO ‘152 teaches that the anti-microbial element of the invention is non-leachably bound to the dispensing device, making it completely ineffective in imparting antimicrobial activity to the skin when a solution is administered to the skin using the disclosed device. The solution being administered does not contain the disclosed antimicrobial element, since the antimicrobial element is attached to the dispensing device; it does not leach into the solution. The exemplified anti-microbial elements include membrane filters, the use of which in no way suggests applying the filter’s antimicrobial properties the skin.

Secondly, WO ‘152 does not teach antimicrobial solutions that can be administered to the skin. In the previous Action, the Examiner stated that the WO ‘152 formulations “are readily used topically directly or indirectly (see page 27 last para – page 28 1st para). In fact, Sawan spreads the compositions directly into the eye (see page 60, claims 29 – 30).” Applicants, once again, respectfully point out that this is not what is taught in WO ‘152. WO ‘152 does NOT teach that these materials “are readily used for topical applications.” The last paragraph on page 27 teaches the liquid dispensers having a non-leachably attached antimicrobial coating and that this dispenser may be filled with a solution, such as a preservative-free sterile eye care liquid. The fact that WO ‘152 exemplifies a liquid that may be used in the dispenser does not teach or suggest that

that liquid is antibacterial, or that that liquid contains any of the components as taught as a coating for an element in the dispenser.

In addition, WO '152 teaches that the solutions preferably do not contain antimicrobials. In the example demonstrating a solution that can be administered to the skin (an eye care liquid), it teaches that the liquid used in the dispenser is preservative free (WO '152 pg. 27 lines 25-26). WO '152 further teaches how to substantially reduce the amount of dissolved silver (an antimicrobial) in the solution by passivating the silver coated surface (pg 22 lines 23 – 25). Therefore, since WO '152 teaches solutions that do not have antimicrobial activity and will not gain antimicrobial activity once applied to the skin, these solutions do not anticipate the present claims.

The background section of WO '152 describes three ways of dispensing sterile solutions: single dose dispensers (page 1, 3rd para), adding preservatives to the solution (page 1, 4th para), and a membrane filter used in the dispenser (page 2, 1st para). Since adding preservatives to the solution are often toxic to mammalian cells (page 1, 4th para), the WO '152 publication teaches a novel device useful for obtaining sterile solutions by the third way; WO '152 teaches the use of membrane filters and other non-leachable antimicrobial elements for inhibiting microbial contamination. The single paragraph in the background section discussing adding preservatives to the solution as a means for maintaining liquid sterility is insufficient anticipate the present invention and cannot be combined with Fujiwara or Smith to make the present invention obvious.

There is no suggestion or motivation to combine the antimicrobial dispensing device taught by WO '152 where antimicrobials in the solution are unnecessary and can be undesirable with the topical formulations of Fujiwara or Smith. The dispenser is not used for the same purpose as the topical compositions of Fujiwara or Smith.

Similarly, any combination of the solutions described in WO '152 and the topical compositions of Fujiwara or Smith do not make the claims of the present invention obvious since these references do not teach or inherently provide a solution that will form a moisture resistant film on the skin containing a substantially-water insoluble antimicrobial metallic material or a metallic

material comprising a metal selected from the group consisting of a silver, zinc, cadmium, lead, mercury, antimony, gold, aluminum, copper, platinum, and palladium. Therefore, new claims 103 – 109 and 111 – 124 are similarly not obvious over WO '152 in view of Fujiwara or Smith.

Therefore, applicants respectfully request that the rejection under 35 U.S.C. §103(a) for claims 58, 60, 62-71, and 89-102 be withdrawn.

Double-Patenting

All claims have been rejected by the Examiner under the judicially created doctrine of obviousness-type double-patenting as being allegedly unpatentable over various claims in commonly-owned U.S. Patents 6,180,584; 6,030,632; 5,869,072; and 5,817,325. Upon indication of allowable subject matter in the present application, the allowable subject matter not being patentably distinct from the claims of one or more of the above-cited patents, an appropriate terminal disclaimer will be timely filed.

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Therefore, in view of the above remarks, it is earnestly requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining that the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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